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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,554	04/07/2005	Hiroyuki Sato	10936-86	8861

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EXAMINER	
MESH, GENNADIY	

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1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,554	SATO ET AL.	
	Examiner	Art Unit	
	GENNADIY MESH	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 6-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 6-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2008 has been entered.

Claims 2, 3 and 5 are cancelled. Claims 23-25 are newly added. Claims 1,4 and 6-25 are active.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1,4, 6 and 10 - 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) combine with Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94(hereafter HTP).

Regarding Claims 1 and 24 Shinoda discloses process for preparation (see abstract) of a polyester with desirable MW(molecular weight) or melt viscosity(note, that melt viscosity of a **resulting aliphatic polyester** polymer is proportional function of the MW of the polyester) from cyclic esters or their mixtures (see lines 5 –15,column 1), in a presence of ring-opening polymerization **catalyst** as, for example, **tin oxide**(see column 6, lines 53 - 55), wherein impurities as water and hydroxycarboxylic acids (

including oligomers) are accurately controlled (thus proton concentration also controlled) with total amount less than 100 ppm (see abstract, lines 40 – 68,column 2, line 5-7,column 3 and line 50,column 6) in order to produce polyester with desirable MW (see lines 1-5,column 3).

Shinoda is silent about addition of water to polymerization system. However, addition of water in order to start ring-opening polymerization process is known in the art. For example, Howelton teach addition of water (as polymerization initiator) in ring – opening polymerization(see line 20,column1).

Therefore, it would have been obvious to one of ordinary of skill in the art to use purified cyclic ester in order to obtain polyester with desirable MW (or melt viscosity) per teaching of Shinoda and add water to polymerization system in order to start or/and increase rate of polymerization as it shown by Howelton.

Shinoda in view of Howelton silent about conducting polymerization in closed volume – particularly inside closed tubes as it claimed by Applicant in Claim 1 and 11.

However, ring –opening polymerization process can be conduct in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process – no volatile byproducts are generated during polymerization process as it disclosed in HTP (pages 90-94).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton inside closed tubes (as a simple polymerization reactors), as it claimed by

Applicant, due to significant reduction of overall cost of production equipment due to simplicity of this type or reactors(tube).

Regarding Claim 12 - Shinoda in view of Howelton silent about conducting polymerization in solid state after initial polymer was produced.

However, solid-state polymerization of polyesters in order to increase MW (or melt viscosity) of the polymer is well known in the art and would be obvious extension of polymerization process as it disclosed in HTP(pages 80 –82).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton with following step of solid-state polymerization as it thought in HTP in order to increase MW of the final polymer.

Subject mater claimed by Applicant in Claims 10 – 16 was discussed above. Regarding Claims 23 - 25 see Shinoda: lines 5-17, column 1; lines 20 – 25,column 6 and Example 6, wherein copolymer of glycolide and other cyclic monomer is disclosed.

Regarding Claims 17 – 20 : Shinoda in view of Howelton discloses substantially same process capable of producing substantially same product as a polyester with same MW. It will be reasonable to believe that other properties as viscosity and Yellowness index will be also substantially same.

3. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) combine with HTP(hereafter HTP), as applied to claims 1,4,6 and 10 –25 above, and further in view of Early (US 6,437,565).

Regarding Claims 7 – 9, Shinoda in view of Howelton combine with HTP discloses that impurities and proton concentration are controlled factor in preparation process of the polyester with desirable MW (or melt viscosity as it explained above – see paragraph 1), but silent about regressional correlation between proton concentration and specific physical properties govern by MW of the polymer.

However, regressional analysis is a standard tool, routinely used in the art in order to determine relations between control factors and any functional properties. For example, Early discloses use of regressional analysis (see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressional analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton combine with HTP.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4.1. Claims 1, 4, 6 and 10 - 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 - 12 of copending Application No. 10/575,468 in view of Shinoda (US 5,412,067) combine with of Howelton (US 5,342,918).

As it was discussed above, claimed subject matter of instant Application 10/530,554 directed to open-ring polymerization of cyclic esters in presence of water at level of no more than 50ppm. Subject matter claimed in Claims 1 and 4-12 of copending Application No. 10/575,468 also directed to open-ring polymerization of cyclic ester in presence of water in the amount of more than 80 ppm.

However, as it was shown in paragraph 2 above open - ring polymerization of cyclic esters in presence of **less than 100 ppm of water** taught by Shinoda combine with Howelton.

Therefore, it would be obvious to one of ordinary skill to conduct open-ring polymerization process in presence of water in quantity less than 50 ppm or quantity more than 80 ppm.

This is a provisional obviousness-type double patenting rejection.

4.2. Claims 1, 4, 6 and 10 - 25 are directed to an invention not patentably distinct from claims 1 and 4 - 12 of commonly assigned copending Application No. 10/575,468 as it shown above(see paragraph 4.1.).

4.3. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned Application No. 10/575,468, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

5. Applicant's arguments filed on December 2, 2008 have been fully considered but they are not persuasive.

5.1. Applicant's arguments related to Claims 1,4, 6 and 10 - 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) combine with Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94(hereafter HTP) based on alleged deficiency of each individual

references and that references " teaches away from any addition of water to cyclic ester".

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Specifically, as it explained in rejection above:

a) Shinoda disclosed process wherein polymer with desirable characteristics is obtained by **controlling impurities that contribute to overall proton concentration:**

"The cyclic ester compound used in the invention is preferably dehydrated as much as possible before subjecting to the polymerization reaction. When the moisture content is high, molecular weight control of polyester is liable to be difficult. Consequently, moisture content of the cyclic ester compound is preferably 0.5% by weight or less, more preferably 1,000 ppm by weight or less. **In order to accurately control the molecular weight of polyester having a molecular weight of 100,000 or more in particular, moisture content of the cyclic ester compound is preferably 100 ppm by weight or less." (Column 6, lines 39-50) .**

Shinoda recognized that Molecular weight can be control if polymerization system contains less than **100 ppm of water** - this amount overlapping with amount of water claimed by Applicant.

Note, that nowhere Shinoda provide teaching that water can not be added to polymerization system. Shinoda stated that water can be present in composition up to 1000 ppm, but preferably up to 100 ppm in order to obtain polymer with relatively high Molecular Weight. Therefore, Shinoda is open to water content in range claimed by Applicant and for this reason Applicant's argument is not persuasive.

b) Shinoda as a Primary reference does not need teach all elements of Applicant's Claims 1, 4,6 and 10-25. Adding water to the polymerization system was taught by Secondary reference as Howelton. Applicant's statement, that one of ordinary skill won't combine disclose of Shinoda with teaching of Howelton is unpersuasive for following reasons: both references belongs to same art of polycondensation by ring-opening mechanism, wherein water can be catalyst of ring opening polycondensation in both processes - this is why one of ordinary skill in the art could apply teaching of Howelton in order to modify process of Shinoda.

Applicant also argue that Howelton does not discuss a production process for producing an aliphatic polyester.

At the same time, Applicant acknowledged that Howelton discloses that water can be used as **initiator in a process** for producing polyamide by **ring-opening polymerization.**

Therefore, teaching of Howelton is applicable to process of ring-opening polymerization disclosed by Shinoda and one of ordinary skill will be motivated to use teaching of Howelton in order to start polymerization.

Regarding Applicant's statement that Shinoda employs ring -opening catalyst and for this reason water as initiator of polymerization is not needed note, that Shinoda stated, that " catalyst are preferably used" - see column 6, line 53 and both, catalyst and initiator can be present (see column 2, lines 40 - 45).

c). HTP is not teaching away from adding water to polymerization system, as it stated by applicant, but provide reasons for conducting ring-opening polymerization process in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process – no volatile byproducts are generated during polymerization process – therefore it would be obvious , **based on this teaching,** to conduct polymerization in closed volume.

d) Note, when ring-opening polymerization is completed, all cyclic structures are opened – than low molecular weight polymers can be subjected to SSP (Solid state polymerization) as it routinely done in the art.

5.2. Regarding Applicant's arguments related to Claims 7-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918)) combine with HTP as applied to claims 1,4,6 and 10 –25 above, and further in view of Early (US 6,437,565).

As it was discussed in rejection, Shinoda in view of Howelton teach that impurities and proton concentration (see above) are controlled factor in preparation process of the polyester with desirable MW, but silent about regressional correlation between proton concentration and specific physical properties govern by MW of the polymer. Note, that regressional analysis is a standard tool, routinely used in the art in

order to determine relations between control factors and any functional properties. For example, Early discloses use of regressional analysis (see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressional analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton combine with HTP.

5.3. Applicant's also argue that process claimed by Applicant provide **unexpected results** as it can be seen from data presented in Table 1, page 43, specifically, from comparison data for volatile matter, melt viscosity, Molecular weight(MW) and yellowness index(YE) .

It is noted, that volatile matter, melt viscosity, molecular weight and yellowness index are not recited in independed Claims 1 and 24 and for this reason , Applicant arguments based on differences in specified properties are not commensurate with scope of the claims 1 and 24.

Same applicable to volatile matter - this property is not recited in any claims.

Regarding Applicant's argument related to melt viscosity and Molecular weight ranges note, that melt viscosity, MW and YE of Comparison Example 3 (see Table 1) inside preferable range of claim 17(melt viscosity) , claims 18 and 20 for MW and claim 19 for YE.

In addition, it is noted that:1) YE can have same value - about 15 (see Examples in Table 1) when process runs **with or without** Dodecyl alcohol; 2) YE in

Example 1 and Example 3 are different by 50% : both process runs with water at same amount (59 ppm), but have **different concentration of impurities** - difference about 40%. 3) concentration of impurities has not been controlled in Comparative Example 3.

Therefore, it would be reasonable to drawn conclusion, that YE is influenced by **concentration of impurities** rather than type of MW control agent as Dodecyl alcohol.

For reasons above, Applicant's argument that claimed process provide unexpected results was found unpersuasive.

Conclusion

THIS ACTION IS NOT MADE FINAL

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GENNADIY MESH whose telephone number is (571)272-2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gennadiy Mesh
Examiner
Art Unit 1796

/GM/

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